REMARKS

Status of Claims

Claims 1, 4, and 8-16 are pending after entry of this paper. Claims 1-3 and 5-7 have been rejected. Claims 4 and 8-16 have been withdrawn and claims 2, 3 and 5-7 have been cancelled without prejudice. Applicant reserves the right to pursue withdrawn and cancelled claims in a divisional or continuing application.

Claim 1 has been amended. Support may be found throughout the instant specification, for example, on page 14 [0021] and original claims 2 and 5 of the application as filed.

No new matter has been introduced by these amendments. Reconsideration and withdrawal of the pending rejections in view of the above claim amendments and below remarks are respectfully requested.

Information Disclosure Statement

The Examiner contends that the Information Disclosure Statement (IDS) filed on 4/28/06 fails to comply with 37 CFR 1.98(a)(2) (*see* Office Action, page 3). Specifically, the Examiner alleges that the JP 07-123985 reference was not submitted. Applicant respectfully disagrees with the Examiner's contentions. The applicant submits herewith a copy of the foreign reference along with the English abstract of the publication which was filed in the US Patent and Trademark Office (USPTO) on 4/28/06. Applicant notes that this copy was obtained from the Image File Wrapper for the instant application using PAIR (from an entry identified as "04-28-2006... FOR... Foreign

Reference..."). The applicant also submits a copy of the IDS and PTO-1449 forms, which were filed in the USPTO on 4/28/06.

As further proof, the applicant submits a copy of the postcard which was stamped by the US Patent and Trademark Office on April 28, 2006, that shows that the reference was received. Specifically, item number 7 states that "PTO-Form 1449A with copies of three (3) cited references" were submitted.

Thus, applicant asserts that the JP 07-123985 reference and English abstract were timely filed with the IDS on 4/28/06. The applicant respectfully requests the consideration of the JP 07-123985 reference.

Response to Rejection under 35 U.S.C. §112, second paragraph

Claims 2-3 and 5-7 are rejected under 35 U.S.C. §112, second paragraph. Specifically, the Examiner contends that the "[i]t is unclear whether the limitations in parentheses are meant to be limitations in the claims or whether they are only suggestions/examples" (*see* Office Action page 4). The applicant has cancelled claims 2-3 and 5-7 without disclaimer of, or prejudice to, the subject matter recited in those claims. Thus, the rejection to these claims is rendered moot.

Claims 2 and 3 are further rejected for allegedly being unclear for the recited terms of "stage of senility (advanced age)" and "transgenic non-human animal (female) until it exhibits a symptom of hyperalbuminemia", respectively (*see* Office Action page 4). The applicant respectfully disagrees with the Examiner's contention.

However, in order to expedite prosecution without disclaimer of, or prejudice to, the subject matter recited in the instant application, the applicant has incorporated the subject matter of claim 2 into claim 1 and has deleted claims 2 and 3. Accordingly, claim 1 as amended is drawn to "a hyperlipemia and/or hyperalbuminemia rat model comprising a homozygote transgenic rat of 36 to 50 weeks of age". Support for a hyperlipemia and/or hyperalbuminemia rat model comprising a transgenic rat being 36 to 50 weeks of age is disclosed in the specification as filed (*see e.g.*, page 14 [0021]). The applicant believes that the rejection of the claims under 35 U.S.C. §112, second paragraph is overcome and respectfully requests reconsideration and withdrawal of the rejection to these claims.

Response to Rejection under 35 U.S.C. §112, first paragraph

Claims 1, 2 and 6-7 are rejected under 35 U.S.C. § 112, first paragraph for alleged lack of enablement. Specifically, the Examiner contends that "the specification does not reasonably provide enablement for claims directed to a transgenic, non-human animal that overexpresses regucalcin and is a model for hyperlipemia and/or hyperalbuminemia" (*see* Office Action at page 5). Applicant respectfully disagrees with the Examiner's contention.

In order to expedite prosecution without disclaimer of, or prejudice to, the subject matter recited in the instant application, the applicant has amended claim 1 to be directed to "a hyperlipemia and/or hyperalbuminemia rat model comprising a homozygote transgenic rat of 36 to 50 weeks of age into which a regucalcin gene is

introduced and which overexpresses regucalcin." Support can be found throughout the specification and claims as filed, for example on pages 19-22 and claims 2 and 5 of the application as filed. Applicant respectfully directs the Examiner's attention to the current Office Action, where the Examiner admits: "[t]he specification discloses on page 19-22, the generation of a transgenic rat overexpressing regucalcin as a tool for to obtain fundamental knowledge of the onset mechanisms of hepatic diseases and hyperlipemia at the stage of advanced age" (*see* Office Action at page 5). Therefore, it is believed that the rejection concerning enablement under 35 U.S.C. § 112, first paragraph has been overcome and, as such, applicant respectfully requests reconsideration and withdrawal of the 35 U.S.C. § 112, first paragraph rejection to claims 2-3 and 5-7.

Response to Rejection under 35 U.S.C. §102(b)

Claims 1-3 and 5-7 are rejected under 35 U.S.C. §102(b) for allegedly being anticipated by Yamaguchi et al. (J. Cell. Biochem. 86: 520-529). The Examiner contends that Yamaguchi et al. teaches all the claimed limitations and anticipates applicant's claimed invention (*see* Office Action, p.13-14). Applicant respectfully disagrees with the Examiner's contention.

In response, applicant hereby submits that amended claim 1 recites: "a hyperlipemia and/or hyperalbuminemia rat model comprising a homozygote transgenic rat of 36 to 50 weeks of age into which a regucalcin gene is introduced and which overexpresses regucalcin". Applicant asserts that Yamaguchi et al. does not teach all of the elements of the instant claims. Specifically, Yamaguchi et al. does not teach or disclose a "hyperlipemia and/or hyperalbuminemia rat model" nor does Yamaguchi et al.

teach or disclose a "transgenic rat of 36 to 50 weeks of age". Thus, Yamaguchi et al. does not teach or disclose each and every element of the instant claims.

Applicant respectfully directs the Examiner's attention to MPEP § 2111.02(I), which states (in relevant part) "[a]ny terminology in the preamble that limits the structure of the claimed invention must be treated as a claim limitation." Yamaguchi et al. does not teach or disclose a hyperlipemia and/or hyperalbuminemia rat model. In fact, Yamaguchi et al. simply utilizes regucalcin-introduced transgenic rats to analyze protein expression levels compared to wild-type rats and merely reports the effects of regucalcin over-expression due to the regucalcin gene introduction. Thus, the applicant asserts that the transgenic rats described in Yamaguchi et al. were not used as animal models for hyperlipemia and/or hyperalbuminemia.

Furthermore, Yamaguchi et al. only analyzed transgenic rats that were 5-6 week old (p. 522, col. 1, paragraph 3), whereas the homozygote transgenic rats of the instant application are 36-50 weeks of age. That is, the transgenic rat of the instant claims is not disclosed in Yamaguchi et al. Also, applicant points out that, in Yamaguchi et al., the concentrations of triglyceride, free cholesterol, and albumin in the transgenic rats were similar to those of wild-type rats (p. 526, col. 2, paragraph 2 and p 528, Table 1), whereas in the instant application the levels of these components are significantly increased in the transgenic rats compared to wild-type (p. 22 [0034] and p. 23 Table 1 of the application as filed). Thus, Yamaguchi et al. does not explicitly or inherently teach or disclose the elements or structure of the instant claims.

Applicant respectfully requests reconsideration and withdrawal of the 35 U.S.C. §102 rejection to claims 1-3 and 5-7 in view of the above-mentioned amendments and remarks.

Response to Provisional Non-Statutory Double Patenting Rejection

Claims 1, 2, and 5-7 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 25, 27, 28, 29, 30, and 33 of copending Application No. 10/804,515. Since the conflicting claims have not in fact been patented, this is a provisional obviousness-type double patenting rejection.

In response, applicant respectfully requests that the provisional double-patenting rejection be held in abeyance due to the provisional nature of the rejection until one of the applications is allowed. Upon notice of otherwise allowable subject matter, applicant will address the rejection. Applicant notes that it is proper when dealing with otherwise allowable subject matter in co-pending applications to withdraw a provisional rejection in the most advanced application, allow it to issue, and make a (non-provisional) rejection in the remaining application.

Dependent Claims

The applicant has not independently addressed all of the rejections of the dependent claims. The applicant submits that for at least similar reasons as to why the independent claims from which all of the dependent claims depend are believed

allowable as discussed *supra*, the dependent claims are also allowable. The applicant however, reserves the right to address any individual rejections of the dependent claims and present independent bases for allowance for the dependent claims should such be necessary or appropriate.

Thus, applicant respectfully submits that the invention as recited in the claims as presented herein is allowable over the art of record, and respectfully request that the respective rejections be withdrawn.

CONCLUSION

Based on the foregoing amendments and remarks, applicant respectfully requests reconsideration and withdrawal of the rejection of claims and allowance of this application. Favorable action by the Examiner is earnestly solicited.

AUTHORIZATION

The Commissioner is hereby authorized to charge any additional fees which may be required for consideration of this Amendment to Deposit Account No. **13-4500**, Order No. 4439-4042.

In the event that an extension of time is required, or which may be required in addition to that requested in a petition for an extension of time, the Commissioner is requested to grant a petition for that extension of time which is required to make this response timely and is hereby authorized to charge any fee for such an extension of time or credit any overpayment for an extension of time to Deposit Account No. **13-4500**, Order No. 4439-4042.

Respectfully submitted,
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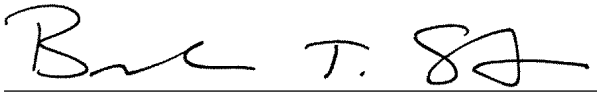
Dated: May 27, 2008 By: 

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